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EXAMINER	
GOLLAMUDI, SHARMILA S	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 11/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/765,463	KRYGER, ABRAHAM H.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13,16,17 and 20* is/are pending in the application.

4a) Of the above claim(s) *14-15, 18-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,16,17 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/6/04*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of the IDS filed 7/6/05 and Election Response is acknowledged. Claims **1-13, 16-17, and 20** are pending. Claims 14-15 and 18-19 are withdrawn as being directed to a nonelected species.

Election/Restrictions

Applicant's election without traverse of the species progesterone in the reply filed on 10/21/05 is acknowledged. Upon further consideration, the species directed to DHEA has been rejoined. Only claims 14-15 and 18-19 remain withdrawn.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 7/6/05 has been considered by the examiner.

Priority

Priority claim as a continuation to US 6,743,448 which claims benefit to provisional application 60/254713 is acknowledged.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-8, 11, 13, and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fossel (5,922,332) in view of Peat (4,628,052) in further view of Crandall (6,316,428).

Fossel teaches topical delivery of arginine, which includes L-arginine, L-arginine salts, and L-arginine derivatives, to overcome pain when topically applied to the area. See abstract and claim 1. The composition in the use of a topical cream, gel, or vehicle, which contains substances such as L-arginine for the purpose of producing beneficial effects such as relief of pain. Fossel discloses that it was discovered that topical application of the nitric oxide precursor, L-arginine, in its various forms including a variety of topical preparations, either by themselves or with other agents, can overcome pain when administered to painful areas of the body. See column 1, lines 45-55. Fossel teaches a variety of means for effecting absorption of the active agent from the topical cream may be used. Examples of packaging which would be carried into tissue includes liposomes or emulsions, collagen peptides or other components of skin or basement membrane. See column 3, lines 10-25. Fossel teaches the use of other active agents in addition to L-arginine. **L-arginine hydrochloride** is used in the amount of **0.25-25%.** Additionally, Fossel teaches the use of **vitamin E in** the amount of **0.02-4%** in the topical vehicle. See claim 8.

Firstly, Fossel does not teach instantly claimed testosterone or the dependent limitations of DHEA or progesterone. Secondly, Fossel does not teach the instant lecithin organogel modified by a polyoxamer.

Peat teaches a compositions for treating rheumatoid arthritis, osteoarthritis, and arthritis associated with psoriasis and with lupus, other auto-immune diseases, and non-specific joint pain associated with stress or incidental to another ailment, comprising steroids administered topically or orally. See abstract. Examples of suitable steroids include dehydroepiandrosterone (DHEA), iso-androsterone, etiocholanolone, progesterone, pregnenolone, and combinations. Peat teaches that when the patient being treated is male, combinations containing **testosterone** are preferably used. See column 2, lines 29-34. A preferred composition for topical use comprises 5% **DHEA**, 80% mixed **tocopherols**, up to 3% **progesterone**, up to about 0.5% **testosterone**, and olive oil. See column 3, lines 20-25 and examples. Peat teaches the use of **micropulverized** forms of the steroid, which reads on "micronized". The proportion of therapeutically active to carrier substance can vary between about 1% and about 99% by weight. The compositions can be prepared in various pharmaceutical forms, including suspensions, salves, lotions, etc.. Peat teaches the use of known pharmaceutical excipients including carriers, diluents, stabilizing agents, emulsifying agents, buffers for securing an adequate pH value, and skin penetration enhancers can be used in formulating the composition. The compositions may further contain other therapeutically active compounds, e.g. selected from the group of drugs commonly used in the treatment of arthritis. See column 2, lines 40-60.

Crandall teaches compositions for topically treating and moisturizing keratinous structures of humans and animals including skin, hair, fingernails, and toenails with a composition comprising water dispersible lecithin. See abstract. Crandall teaches the composition comprising lecithin may be used for treating dry skin, treating wrinkles, psoriasis. Further, the composition also may be used enhancing the penetration of pharmacologically active

substances into keratinous tissue, especially the epidermis and dermis of the skin, without damaging the tissue or causing adverse systemic effects see column 3, lines 40-57. The "enhanced penetration" of the composition into the skin is achieved with compounds such as lecithin organogel, poloxamer organogel, phospholipid gels or poloxamer phospholipid gels. See column 5, lines 49-60. Specifically, the examples utilize a lecithin organogel prepared with Pluronic (a polyoxamer). Crandall teaches the term "pharmacologically active agent" relates to any chemical material or compound suitable for topical administration and the composition may be in any form including liquid, gel, salve, solvent, liquid, diluent, fluid ointment base, liposome, etc. see column 5, lines 33-44. Crandall teaches the use of actives such as arginine and Vitamin E tocopherol (see column 9, line 14 and 23) and preservative including vitamin E tocopherol.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Fossel, Peat, and Crandall. Firstly, it would have been obvious to look to the teaching of Peat and utilize instant steroid combination of testosterone, progesterone, and DHEA. One would have been motivated to do so since Peat teaches the use of DHEA and progesterone to treat arthritis and joint pain and the additional use of testosterone if the patient is male. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose to form a third composition for the same purpose." See In re Kerkhoven, 626 F. 2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Thus, it would have been obvious to a skilled artisan to utilize progesterone and testosterone in Fossel's composition with an expectation of at least an additive effect in treating pain. Moreover, a skilled artisan would have reasonably expected success by the instant combination since both Fossel and Peat suggest additional active agents in the respective arthritis and pain treating

composition. Lastly, although Peat does not specify that the testosterone itself is micropulverized, the examiner points out that testosterone is in a crystalline powder form. See Remington Pharmaceutical Sciences as art of interest to show this implicit property of testosterone. Thus, this limitation is met since applicant's claim is broadly directed to "micronized testosterone" without reciting a specific particle size.

Secondly, it would have been obvious for one of ordinary skill in the art at the time the invention was made to further look to the teachings of Crandall and utilize a polyoxamer and lecithin organogel. One would have been motivated to do so since Crandall teaches a composition that may be used to enhance the penetration of pharmaceutical agents such as arginine and vitamin E into the skin and the polyoxamer/lecithin organogel provides this penetration enhancing effect. Therefore, a skilled artisan would have been motivated to add the instant a polyoxamer/lecithin organogel to increase the penetration of the composition into the skin. Moreover, a skilled artisan would have expected success by the instant combination since both Fossel and Peat suggest any means of effecting penetration of the active into the skin might be utilized.

With regard to the instant recitation "wherein application of from about 0.5g to about 2g of the formulation to the skin, produces physiologic testosterone serum levels..." and claim 2, the examiner points out that the claims are directed to a product and the instant recitation is "intended use", which is not given patentable weight unless it imparts a structural limitation. In instant case, the claim limitation is not providing a structural limitation to the product itself and rather the limitation is toward the methodology of use, i.e. *when the product in applied* in a certain amount it produces a certain serum level.

With regard to the recitation of "a testosterone aromatization-inhibiting amount of a tocopherol", the instant specification on page 16 states that 0.1-20% tocopherol may be added is to reduce or minimize the aromatic conversion of testosterone. Fossel teaches the use of 0.02-4% Vitamin E. Further, it should be noted that Peat also teaches the combination of testosterone and various amount of tocopherols.

With regard to claim 8, although Fossel teaches 0.02-4% of vitamin E, Fossel does not teach the instant *about* 5%. Firstly, it is the examiner's position that "about 5%" is in an obvious range of the prior art's 4%. Moreover, it would have been obvious to a skilled artisan in the art at the time the invention was made to manipulate the amount of Vitamin E in the composition. The manipulation of parameters during routine experimentation such as concentration of an individual component, wherein an obvious range is taught by the prior art, is considered prima facie obvious absent the showing of the unexpectedness of the instantly claimed concentration. "Generally difference in concentrations do not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such as concentration is critical." See In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fossel (5,922,332) in view of Peat (4,628,052) in further view of Crandall (6,316,428) in further view of Quan (6,180,133).

The teachings of Fossel, Peat, and Crandall have been set forth above. In particular, Fossel teaches a topical composition comprising L-arginine and a vehicle including 0.02-4% vitamin E, for treating pain. Peat teaches a composition comprising 3% progesterone and 0.5%

testosterone to treat pain and arthritis. Crandall teaches a topical composition to enhance penetration of active agents using a polyoxamer and lecithin organogel in a topical composition.

Fossel does not specify the form of vitamin E, i.e. if it is alpha tocopherol or gamma tocopherol. Further, Peat teaches a tocopherol mixture may be used with the steroids but not specify what this mixture is.

Quan teaches an antioxidant composition for topical use. See abstract. Quan teaches vitamin E may be used in any suitable form such as alpha or gamma tocopherol as an antioxidant. Quan teaches vitamin E is conventionally utilized in the amount of 1-10%. See column 5, line 65- column 6, line 2 and column 25, lines 25-30.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to further look to the teaching of Quan and utilize either gamma or alpha tocopherol. One would have been motivated to utilize either form of vitamin E since Quan teaches that either gamma or alpha tocopherol are effective and suitable for topical use. Moreover, Quan demonstrates the prior art wherein the use of either form of vitamin E is known and utilized in the art. Thus, a skilled artisan would have reasonably expected success by the use of either form of tocopherol.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fossel (5,922,332) in view of Peat (4,628,052) in further view of Crandall (6,316,428) in further view of Rosenbaum (5,869,090).

The teachings of Fossel, Peat, and Crandall have been set forth above. In particular, Fossel teaches a topical composition comprising L-arginine and a vehicle including 0.02-4% vitamin E, for treating pain. Peat teaches a composition comprising 5% DHEA, 3% progesterone

and 0.5% testosterone to treat pain and arthritis. Crandall teaches a topical composition to enhance penetration of active agents using a polyoxamer and lecithin organogel in a topical composition.

Although Peat teaches the topical use of DHEA for treating rheumatoid arthritis, Peat does not teach the use of DHEA sulfate.

Rosenbaum teaches the topical delivery of DHEA for the treatment of conditions including rheumatoid arthritis. See abstract and column 3, line 30. Rosenbaum teaches the dehydroepiandrosterone compound suitable for the topical composition include DHEA itself and DHEA sulfate. See column 3, lines 44-46.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to further look to the teaching of Rosenbaum and utilize a dehydroepiandrosterone derivative such as instant DHEA sulfate. One would have been motivated to utilize DHEAS since Rosenbaum teaches any form of dehydroepiandrosterone including DHEAS, is suitable for topical use. Moreover, Rosenbaum teaches the dehydroepiandrosterone compound is used for treating conditions including rheumatoid arthritis. Therefore, a skilled artisan would have been motivated to utilize either DHEA or the derivative form of DHEAS with the reasonable expectation of success since Rosenbaum either form is suitable for the topical treatment of conditions such as arthritis.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fossel (5,922,332) in view of Peat (4,628,052) in further view of Crandall (6,316,428) in further view of WO 99/20257 to Samour.

The teachings of Fossel, Peat, and Crandall have been set forth above. In particular, Fossel teaches a topical composition comprising L-arginine and a vehicle including vitamin E, for treating pain. Peat teaches a composition comprising 3% progesterone and 0.5% testosterone to treat pain and arthritis. Crandall teaches a topical composition to enhance penetration of active agents using a polyoxamer and lecithin organogel in a topical composition.

The combined references do not teach the instant amount of testosterone.

Samour teaches a hormone replacement composition for topical application to the skin. The hormones utilized include testosterone utilized for hypogonadism, muscle wasting, etc, DHEA for muscle wasting, progesterone, etc. see page 8. The hormone is utilized in an amount of 0.1-10%. See page 6, lines 19-20.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to further look to the teachings of Samour and utilize the instant amount of testosterone. One would have been motivated to do so with a reasonable expectation of success since Samour teaches hormones including the instant testosterone can be used in the amount of 0.1-10% in a topical composition. Further, Samour teaches the topical use of testosterone for the treatment of muscle wasting. Therefore, a skilled artisan would have been motivated to increase the concentration of the testosterone in the composition without expecting an adverse effect since the prior art teaches that a range of 0.1-10% of testosterone may be used topically.

With regard to instantly claimed *about* 5%-10% tocopherol, although Fossel teaches 0.02-4% of vitamin E, Fossel does not teach the instant *about* 5%. Firstly, it is the examiner's position that "about 5%" is in an obvious range of the prior art's 4%. Moreover, it would have been obvious to a skilled artisan in the art at the time the invention was made to manipulate the

amount of Vitamin E in the composition. The manipulation of parameters during routine experimentation such as concentration of an individual component, wherein an obvious range is taught by the prior art, is considered prima facie obvious absent the showing of the unexpectedness of the instantly claimed concentration. "Generally difference in concentrations do not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such as concentration is critical." See In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-13, 16-17, and 20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 10/765004. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant independent claim is directed to a topical testosterone formulation comprising: (A) a modified poloxamer lecithin organogel carrier having admixed therein; (B) a therapeutically effective amount of an arginine ingredient; (C) a testosterone aromatization inhibiting amount of a tocopherol ingredient; and (D) an amount of micronized testosterone of from about 0.5% w/w to about 25% w/w. Dependent claim 3 is directed to arginine in the amount of 0.1% w/w to about 20%. Dependent claim 4 is directed to the arginine ingredient in an amount of about 5% w/w to about 10%. Dependent claim 5 is directed to a salt form arginine and dependent 6 is directed to L-arginine monochloride. Dependent claim 7 is directed to tocopherol in the amount of about 0.1% w/w to about 20% and dependent 8 is directed to tocopherol in the amount of about 5% w/w to about 10% w/w. Dependent claim 9 is directed specifically to alpha tocopherol and claim 10 is directed specifically to gamma tocopherol. Dependent claim 11 is directed to the composition further comprising dehydroepiandrosterone (DHEA) and claim 12 is directed to dehydroepiandrosterone sulfate (DHEAS). Dependent claim 13 is directed to DHEA in the amount from 1% w/w to about 20% w/w of the formulation. Dependent claim 16 is directed to the composition further comprising an effective amount of progesterone and claim 17 is directed to about 1% w/w to about 20% w/w progesterone. Dependent claim 20 is directed to testosterone in the amount of about 5% w/w to about 10% w/w, the amount of tocopherol is from about 5% w/w to about 10% w/w, and the amount of arginine is from about 5-10% of the formulation.

Copending application independent claim is directed to a topical testosterone formulation comprising: (A) a modified poloxamer lecithin organogel carrier having admixed therein; (B) a therapeutically effective amount of an arginine ingredient in the amount of 0.1-20%; (C) a

tocopherol in the amount of 0.1-20%; and (D) an amount of micronized testosterone. Dependent claim 2 is directed to testosterone in the amount of 0.5-25% and dependent claim 3 is directed to 5-10% testosterone. Dependent claim 4 is directed to a salt form arginine and dependent 5 is directed to L-arginine monochloride. Dependent claim 6 is directed to arginine in the amount of about 5% w/w to about 10%. Dependent claim 7 is directed specifically to alpha tocopherol and claim 8 is directed specifically to gamma tocopherol. Dependent claim 9 is directed to tocopherol in the amount of 5-10%. Dependent claim 10 is directed to the composition further comprising dehydroepiandrosterone (DHEA) and claim 11 is directed to dehydroepiandrosterone sulfate (DHEAS). Dependent claim 12 is directed to DHEA in the amount from 1% w/w to about 20% w/w of the formulation. Dependent claim 15 is directed to the composition further comprising an effective amount of progesterone and claim 16 is directed to about 1% w/w to about 20% w/w progesterone. Dependent claim 19 is directed to testosterone in the amount of about 5% w/w to about 10% w/w, the amount of tocopherol is from about 5% w/w to about 10% w/w, and the amount of arginine is from about 5-10% of the formulation.

Thus, the instant application and copending application '004 are directed to overlapping subject matter wherein both application claim a topical composition comprising (A) a modified poloxamer lecithin organogel carrier, (B) a therapeutically effective amount of an arginine ingredient, (C) a tocopherol, and (D) micronized testosterone. The dependent claims of the respective application claim the same weight percents of each component and the same additional actives such as DHEA and progesterone. Furthermore, the instant claims have open claim language, i.e. comprising; thus the instant claims are open to additional active agents such

as those claimed in copending application (melatonin and oxytocin) wherein the instant claims would encompass the claims of '004.

It should be noted that instant claims 14-15 and 18-19 are not rejected under double patenting since they are withdrawn as being directed to nonelected species; however it is noted that these claims have double patenting issues with the '004 and if the species are rejoined, the claims will be rejected under obviousness double patenting.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-10 and 20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of copending Application No. 10/765003. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant independent claim is directed to a topical testosterone formulation comprising: (A) a modified poloxamer lecithin organogel carrier having admixed therein; (B) a therapeutically effective amount of an arginine ingredient; (C) a testosterone aromatization inhibiting amount of a tocopherol ingredient; and (D) an amount of micronized testosterone of from about 0.5% w/w to about 25% w/w. Dependent claim 3 is directed to arginine in the amount of 0.1% w/w to about 20%. Dependent claim 4 is directed to the arginine ingredient in an amount of about 5% w/w to about 10%. Dependent claim 5 is directed to a salt form arginine and dependent 6 is directed to L-arginine monochloride. Dependent claim 7 is directed to tocopherol in the amount of about 0.1% w/w to about 20% and dependent 8 is directed to tocopherol in the amount of about 5% w/w to about 10% w/w. Dependent claim 9 is directed specifically to alpha

tocopherol and claim 10 is directed specifically to gamma tocopherol. Dependent claim 11 is directed to the composition further comprising dehydroepiandrosterone (DHEA) and claim 12 is directed to dehydroepiandrosterone sulfate (DHEAS). Dependent claim 13 is directed to DHEA in the amount from 1% w/w to about 20% w/w of the formulation. Dependent claim 16 is directed to the composition further comprising an effective amount of progesterone and claim 17 is directed to about 1% w/w to about 20% w/w progesterone. Dependent claim 20 is directed to testosterone in the amount of about 5% w/w to about 10% w/w, the amount of tocopherol is from about 5% w/w to about 10% w/w, and the amount of arginine is from about 5-10% of the formulation.

Copending '003 independent claim is directed to method of treating a disease or condition which is responsive to testosterone therapy comprising the step of: administering a topical testosterone formulation to the skin of a subject, wherein the formulation comprises a (A) a modified poloxamer lecithin organogel carrier having admixed therein; (B) an arginine ingredient in an amount of from about 0.1 to about 20%; (C) and a tocopherol ingredient in an amount of from about 0.1 to about 20%; (D) and a therapeutically effective amount of micronized testosterone. Dependent claim 17 is directed to the method of claim 1, wherein the formulation has testosterone in the amount of about 10% w/w and administration is a routine of administering from about 0.5 g to about 2 g. Independent claim 22 is directed to a method of temporarily and reversibly decreasing sperm count comprising the step of: administering a topical testosterone formulation to the skin of a male, wherein the formulation comprises (A) a modified poloxamer lecithin organogel carrier having admixed therein; (B) an arginine ingredient in an amount of from about 0.1 to about 20% w/w; (C) and a tocopherol ingredient in

an amount of from about 0.1 to about 20% w/w, and a therapeutically effective amount of micronized testosterone.

Copending application '003 claim 1 and 17 render a scope of administering a composition comprising (A) a modified poloxamer lecithin organogel carrier having admixed therein; (B) an arginine ingredient in an amount of from about 0.1 to about 20%; (C) and a tocopherol ingredient in an amount of from about 0.1 to about 20%; (D) and about 10% micronized testosterone. Thus, the method claims anticipate the instant composition claims since the method claims require the same composition as instantly claimed to practice the methodology; thus one must necessarily have possession of the composition to practice the methodology. With regard to claim 22, the specification of '463 defines the therapeutic effective amount is 0.5-25% and thus the method claims anticipated by the instant composition claims. With regard to instant dependent claim 5 and 6, the use of arginine derivatives such as salts, i.e. monochloride is an obvious variant. Further, '003 broadly recite arginine and thus the instant arginine salts are encompassed by copending application. With regard to instant dependent claim 9 and 10, '003 claims broadly claims a tocopherol ingredient, which encompasses the instant alpha and gamma tocopherol.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US20020165429 to Thompson filed on December 14, 2000 is made to record for administering L-arginine, menthol, and testosterone but is not prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
Examiner
Art Unit 1616